K020825
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Instromedix®
A Card Guard Company

Today's
Telemedicine
Solutions

APR - 5 2002

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"510(k) Summary"

As Required By Section 807.92(c)

Contact Person: **Alden Kay**

Date March 11, 2002

Trade Name: **King of Hearts® Express + AF Monitor or TBD**

Common Name: *Telephone Electrocardiograph Recorder and Transmitter*

Classification Name: *Telephone Electrocardiograph Transmitter and Receiver (Per 21 CFR section 870.2920)*

Predicate Devices: **King of Hearts® Express Monitor (K920984) and King of Hearts® Express II Monitor (K983626) [Instromedix]**

[21 CFR 807.92(a)(3)] **The King of Hearts® Express + AF Monitor is equivalent to our predicate devices in that this device is a looping recorder utilizing ECG data acquisition for recording and playback. The FSK (Frequency Shift Keying), Center Frequency, and Transmission Protocol are the same as that of our predicate device. The fundamental scientific technology of the device has not been altered with this modification of our predicate devices.**

Device Description Summary

[21 CFR 807.92(a)(4)] **The King of Hearts® Express + AF Monitor is an auto triggered cardiac event recorder designed for diagnostic evaluation of transient symptoms. The device uses a two-wire single channel lead set for event recording. Using looping memory, the device captures ECG data; auto triggering `after the patient experiences a cardiac symptom or manually after the patient pushes the RECORD button. The number of Events can be physician adjusted according to the programmed lengths of Before and After data acquisition duration for each recording. These segments of stored ECG can then be transmitted later in the form of an FM-modulated acoustic tone, when the SEND button is manually depressed. The device is configured in the same compact sized case approximately 4 inches long, 2 ¾ inches wide and 5/8 " thick as the predicate devices. The two wire lead set is the same as is used in the predicate device [King of Hearts® Express Monitor (K920984)].**

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Device Intended Use:

[21CFR 807.92(a)(5)] **The device is indicated for diagnostic evaluation of patients who experience transient symptoms such as; dizziness, palpitations, syncope, chest pain.**

The device is contra-indicated for use in combination with an external cardiac defibrillator or high frequency surgical equipment.

The INDICATION/INTENDED USE and CONTRA-INDICATIONS of the modified device HAS NOT CHANGED.

Similarities to Predicate Device:

[21CFR 807.92(a)(6)] **This device has the same basic technological characteristics as the predicate devices. The differences are *a*) Addition of atrial fibrillation (AF) detection, *b*) Modified total ECG recording time.**

Safety and Effectiveness: The King of Hearts® Express + AF Monitor is considered safe and effective for use when used in accordance with the instructions provided in the Owners Manual which accompanies each device. This device is a modification of previously cleared products currently manufactured by Instromedix. The only modifications are stated above. Based on these minor changes, there is no impact on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 5 2002

Mr. Alden Kay
Director, Quality
Card Guard Scientific Survival Ltd
Instromedix
6779 Mesa Ridge Road, Suite 200
San Diego, CA 92121-2909

Re: K020825
Trade Name: King of Hearts® Express + AF Monitor
Regulation Name: Medical Magnetic Tape Recorder
Regulation Number: 21 CFR 870.2800
Regulatory Class: Class II (two)
Product Code: DSH
Dated: March 13, 2002
Received: March 14, 2002

Dear Mr. Kay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

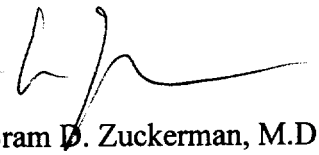
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020825

Device Name: **King of Hearts® Express + AF Monitor**

Indications for Use

This device is indicated for diagnostic evaluation of patients who experience transient symptoms such as;

- Dizziness
- Palpitations
- Syncope
- Chest pain

Contra-Indications for Use

Warning:

This device is contra-indicated for use in combination with external cardiac defibrillators or high frequency surgical equipment. Disconnect the patient leads from the electrodes prior to performing external defibrillation or using electro surgical equipment.

There are no known safety hazards connected with the use and operation of a cardiac pacemaker or any electrical cardiac stimulator and the **King of Hearts® Express + AF** monitor.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020825